Mitchell E. Daniels, Jr. Governor

Judith A. Monroe, M.D. State Health Commissioner



IN RE THE MATTER OF:

Rachelle Karpeles f'REAL! Foods 37 Avenida de Orinda Orinda, CA 94563

Re: Variance Request Dated June 12, 2008 and Section 296,

Equipment food-contact surfaces and utensils; frequency requirements

Order to Grant a Variance

You are hereby notified that based on the recommendation of the Food Protection Program, Indiana State Department of Health (ISDH), and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be issued to Rachelle Karpeles, f'REAL! Foods, 37 Avenida de Orinda, Orinda, CA 94563.

This variance is based on the variance application submitted on June 12, 2008. As part of the review of variance application, an ISDH representatives conducted an on-site evaluations to determine how the procedures put into place were being administered and monitored. In addition, the f'REAL! Foods agreed to do additional research studies on this equipment.

<u>Order</u>

This variance is subject to the following terms and conditions and is valid only for this company as specified herein:

- 1. A variance Order is hereby issued to Rachelle Karpeles, f'REAL! Foods, 37 Avenida de Orinda, Orinda, CA 94563 for the requirement of 410 IAC 7-24-296 which limits to four (4) hours the time that equipment can contact potentially hazardous foods without being cleaned and sanitized. For this variance approval, the time limit will be expanded to 24 hours before the blender equipment must be cleaned and sanitized. Sufficient research documentation demonstrates that this proprietary system does not allow the growth of pathogenic microorganisms on the equipment within the 24 hour time period.
- This variance Order only applies to this machine currently in use and any modifications to the system would have to be approved by the Indiana State Department of Health.
- 3. If new science emerges that demonstrates that this system is no longer safe, or otherwise deemed to be a hazard, this approval Order may be revoked.



- 4. This variance Order is limited to the current owner, or his designee, and the current scope of the existing operations. This variance Order is not transferable to a new owner.
- 5. This variance Order is limited to being in compliance with all other applicable state and local regulations.
- 6. Failure to comply with any of the above conditions could result in the revocation of the variance approval Order.

DATED AT INDIANAPOLIS, INDIANA, THIS 27th DAY OF OCTOBER 2009.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY GRANT A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

JUDITH A. MONROE, M.D.

STATE HEALTH COMMISSIONER

James D. Howell, DVM, MPH

Assistant Commissioner

Public Health and Preparedness Commission

cc: Local Health Department

ISDH Food Protection Program Staff Eldon Whetstone, Office of Legal Affairs